

Notice of Allowability

Application No.

10/019,743

Applicant(s)

SASAKI ET AL.

Examiner

Anand U. Desai, Ph.D.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to December 29, 2004.
2. ☒ The allowed claim(s) is/are 1-19.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20050315</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

1. This office action is in response to Amendment filed on December 29, 2004. New claim 19 has been added. Claims 1-19 are currently pending and are under examination.

Withdrawal of Rejections

2. The rejection of claims 1-16, and 18 under 35 U.S.C. 112, 2nd paragraph is withdrawn based on amendments to the claims.
3. The rejection of claims 16, and 17 under 35 U.S.C. 102(e) as being anticipated by Hutchinson (U.S. Patent 5,889,110) is withdrawn.
4. The rejection of claims 16, and 17 under 35 U.S.C. 102(e) as being anticipated by Hatanaka et al. (U.S. Patent 6,211,333) is withdrawn.

Response to Amendment

5. The Declaration filed on December 29, 2004 under 37 CFR 1.131 is sufficient to overcome the Hatanaka et al. reference (U.S. Patent 6,211,333).

EXAMINER'S AMENDMENT

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Stephana E. Patton on March 21, 2005.

Examiner's Amendment to the Claims:

1. (Currently Amended) A process for preparing a purified LH-RH derivative which comprises the steps of:

contacting a solution containing the LH-RH derivative with a methacrylic synthetic adsorption resin; and contacting the solution containing the LH-RH derivative with an aromatic synthetic adsorption resin, thereby preparing a purified LH-RH derivative.

6. (Currently Amended) The process according to claim 5, wherein an average particle size of the styrene-divinylbenzene, synthetic adsorption resin is about 60 μm ~~pm~~ to about 150 μm ~~pm~~.

7. (Currently Amended) The process according to claim 1, wherein said process comprises subjecting a solution containing the LH-RH derivative ~~to the step for treatment~~ with a methacrylic synthetic adsorption resin below about 10°C.

8. (Currently Amended) The process according to claim 1, wherein said process comprises subjecting a solution containing the LH-RH derivative ~~to the step for treatment~~ with an aromatic synthetic adsorption resin at about 10°C to about 20°C.

9. (Currently Amended) The process according to claim 1, wherein said process comprises subjecting a solution containing the LH-RH derivative ~~to the step for treatment~~ with a methacrylic, synthetic adsorption resin, followed by subjecting ~~to the step for treatment~~ the LH-RH derivative solution with an aromatic, synthetic adsorption resin.

10. (Currently Amended) The process according to claim 1, said process comprises passing a solution containing the LH-RH derivative through ~~a resin~~ the methacrylic synthetic

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adsorption resin in the step of contacting the LH-RH derivative ~~with the methacrylic synthetic~~
~~adsorption resin~~; and then eluting the LH-RH derivative, which is adsorbed on the resin, with an aqueous solution of acetic acid.

12. (Currently Amended) The process according to claim 1, wherein said process comprises passing a solution containing the LH-RH derivative through ~~a resin~~ the methacrylic, synthetic adsorption resin in the step of contacting the LH-RH derivative ~~with a methacrylic, synthetic adsorption resin~~, followed by washing with an aqueous solution of ethanol, and then by eluting the LH-RH derivative that is adsorbed on the resin.

13. (Currently Amended) The process according to claim 1, wherein a solution containing the LH-RH derivative is ~~that~~ obtained by subjecting the LH-RH derivative protected with protective group(s) to a deprotection reaction followed by a neutralization reaction below about 10°C.

14. (Currently Amended) The process according to claim 1, wherein a solution containing the LH-RH derivative is ~~that~~ obtained by subjecting the LH-RH derivative protected with protected group(s) to a deprotection reaction and then a neutralization reaction below about 10°C, followed by subjecting the resulting mixture to extraction of the LH-RH derivative and then concentration of the extract below 25°C.

19. (Currently Amended) The purified leuprorelin ~~leuporelin~~ or a salt thereof according to claim 16, wherein the impurities are racemic isomers of the LH-RH derivatives ~~and/or highly polar related substances~~.

Allowable Subject Matter

7. Claims 1-19 are allowable.

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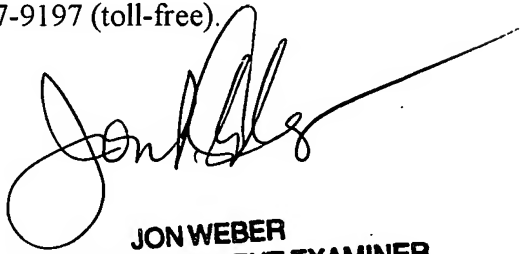
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 21, 2005



JON WEBER
SUPERVISORY PATENT EXAMINER